

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Confirmation No.: 9740

Claes Wallen

Date: August 27, 2007

Serial No.: 10/520,724

Group Art Unit: 3767

Filed: April 15, 2005

Examiner: Elizabeth Macneill

For: A DEVICE FOR INJECTING MEDICAL SUBSTANCES

VIA EFS-WEB

Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

AMENDMENT/SUBMISSION

Sir:

This is a response to the Office Action mailed April 27, 2007 in the above-identified application. Reconsideration of the application is respectfully requested.

FEE CALCULATION

Any additional fee required has been calculated as follows:

If checked, "Small Entity" status is claimed.

	No. Claims After Amendment		Highest No. Previously Paid For		Extra Present		Rate	ADDIT. FEE
TOTAL	11	MINUS	20	* =	0	X	(\$25 SE or \$50)	\$ 0.00
INDEP	2	MINUS	3	** =	0	X	(\$100 SE or \$200)	\$ 0.00
First Presentation of Multiple Dependent Claim						X	(\$180 SE or \$360)	\$ 0.00
* not less than 20 ** not less than 3							TOTAL	\$ 0.00

In the event the actual fee is greater than the payment submitted or is inadvertently not enclosed or if any additional fee during the prosecution of this application is not paid, the Patent Office is authorized to charge the underpayment to Deposit Account No. 15-0700.

CONTINGENT EXTENSION REQUEST

If this communication is filed after the shortened statutory time period had elapsed and no separate Petition is enclosed, the Commissioner of Patents and Trademarks is petitioned, under 37 C.F.R. § 1.136(a), to extend the time for filing a response to the outstanding Office Action by the number of months which will avoid abandonment under 37 C.F.R. § 1.135. The fee under 37 C.F.R. § 1.17 should be charged to our Deposit Account No. 15-0700.

SUMMARY OF AMENDMENTS

1. If checked, an abstract (an amended abstract) is submitted herewith.
2. If checked, amendment(s) to the drawings are submitted herewith.
3. If checked, amendment(s) to the specification are submitted herewith.
4. If checked, amendment(s) to the claims are submitted herewith.

LISTING OF THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Currently Amended) A device for injection, comprising a body (1) provided with a first channel (2) for conveyance of a first medical substance and a first connecting component (3) having a first port (4) for introduction of a first medical substance into said first channel (2), said connecting component (3) being connectable to an external unit, and a second channel (5) for conveyance of a second medical substance and a second connecting component (6) having a second port (7), that has a first flexible membrane (17), which can be opened by means of an injection component for injecting a second medical substance into said second channel (5), and provided with a third connecting component (8) being common to the first and the second channels (2,5) and having at least one third port (9) for conveying medical substances out from said first and second channels, characterized in that said first (3), second (6) and third (8) connecting components and the body (1) are designed as an integrated unit, and said third connecting component (8) is a first luer fitting component provided with a thread (19) for releasable connection with a second luer fitting component having a corresponding thread, for creating a luer fitting coupling, wherein the first channel (2) extends in a generally straight line through the body (1) of the device.
2. (Previously Presented) A device according to claim 1, wherein the body (1) has a channel portion (12) common to the first (2) and the second (5) channels, and said third port (9) constitutes an outlet for this channel portion (12) and thereby an outlet common to the first and the second channels.
3. (Previously Presented) A device according to claim 1, wherein said third connecting component (8a) has a fourth port (23), wherein said third port (9a) constitutes an outlet for the first channel (2a) and said fourth port (23) constitutes an outlet for the second channel (5a).
4. (Currently Amended) A device according to claim 1, wherein said second port (7) has a first flexible membrane (17) for cooperation cooperates with a second flexible membrane

arranged in an injection component (11) which is connectable to said second connecting component (6).

5. (Previously Presented) A device according to claim 4, wherein the device has a means (18) for holding said second flexible membrane with a pressure against said first membrane (17).

6. (Previously Presented) A device according to claim 5, wherein the pressure exceeds the yield point of the first and the second membranes.

7. (Previously Presented) A device according to claim 5, wherein the pressure exceeds 150 kPa.

8. (Currently Amended) A device according to claim 1, wherein the third connecting component (8) comprises a first luer fitting component comprises a male fitting (20) intended to cooperate with a corresponding female fitting of said second luer fitting component, which female fitting has a further channel, to form a connection sealed relative to the environment between the first (2) and the second (5) channels on one hand and said further channel on the other hand.

9. (Previously Presented) A device according to claim 8, wherein the first luer fitting component comprises a ring (21) which is concentrically arranged relative to the male fitting (20) and at least partly encloses the male fitting (20), the ring being provided with said thread (19).

10. (Previously Presented) An injection arrangement comprising a device according to claim 1 for transmitting a first medical substance from an infusion bag (10) connected to said first connecting component (3) of the device, via the first channel (2), to a receiving unit connected to said third connecting component (8) of the device, and for transmitting a second medical substance from an injection component (11) connected to said second connecting component (6) of the device, via the second channel (5), to said receiving unit.

11. (New) An injection device comprising:

a body having a first channel extending in a generally straight line through the body, the channel for conveying a first medical substance;

a first connecting component having a first port for introduction of the first medical substance into said first channel, said first connecting component being connectable to an external unit;

second channel for conveying a second medical substance;

a second connecting component having a second port including a first flexible membrane, wherein the first membrane can be opened by means of an injection component for injecting the second medical substance into said second channel;

a third connecting component being common to the first and the second channels;

at least one third port for conveying the first and second medical substances out from the first and second channels, wherein the first, second and third connecting components and the body are designed as an integrated unit, and the third connecting component is a first luer fitting component provided with a thread for releasable connection with a second luer fitting component having a corresponding thread, for creating a luer fitting coupling.

REMARKS/ARGUMENTS

Claims 1-10 remain pending in the instant application.

Amendments to the Claims

As amended above, claim 1 comprises the features of original claim 1 in the application as filed, and incorporates subject matter from Figures 1, 2a and 3, namely that the second port comprises a first flexible membrane and that the first channel (i.e. the channel that does not comprise the first flexible membrane) extends in a generally straight line through the body (1) of the device. Claim 4 is amended for consistency with the amendments to claim 1.

Claim 8 has been amended by adding the feature that the third connecting component comprises a first luer fitting component, but only for the sake of clarity and not because it is necessary to patentability. Support for this amendment can be found on page 6, lines 28-29 of the description.

Claim 11 is newly presented and incorporates the subject matter of claim 1, including the above noted amendments, presented in more customary form for U.S. examination.

No new matter has been added by these amendments.

Rejection under 35 U.S.C. § 102

Claims 1-10 are rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,254,097 to Schock, et al. (Schock). Applicant respectfully traverses the rejection.

As amended above, claim 1 recites a device for injection having a first channel that extends in a generally straight line through the body of the device, and further a second channel with a second port that has a flexible membrane that can be operated by means of an injection component for injecting a second medical substance in to the second channel. The amended claims are not anticipated by Schock.

Schock does not disclose a device for the injection of two medical substances, preferably liquids, where it is desired to transmit two medical substances from two different sources to a receiving unit. Instead Schock concerns a cannula with multiple access ports for performing multiple simultaneous medical procedures such as percutaneous cardiopulmonary bypass (CPB) and intra-aortic balloon pumping (IABP) (Schock, Col. 1, lines 11-13 and Col. 4, lines 10-13).

In PBY deoxygenated blood is removed through a first cannula inserted in a femoral vein of one of a patient's legs. The deoxygenated blood is fed to an external oxygenator and pump system, and then pumped back into the patient through a second cannula inserted in a femoral artery of one of the patient's legs. In IABP an intra-aortic balloon (IAB) is inserted into the body of a patient through a femoral artery in the groin area of the patient. The IAB then is pushed up through the arterial tree until the balloon is located in the descending thoracic aorta. Inflation and deflation of the balloon causes a pumping action that supplements the natural pumping of the heart. Inflation of the balloon forces blood out of the aorta to other parts of the body. Deflation of the balloon creates a slightly lowered pressure in the aorta, which reduces the back-pressure against which the heart must work during the next pumping cycle.

In contrast to the device disclosed in Schock, the present invention includes a first channel that extends in a generally straight line through the body of the device. As described in the specification, it is often desired to place the first channel vertically, so that fluid transportation from an infusion bag can be facilitated. There is no corresponding channel generally straight through the body of Schock together with a second channel including a second port that has a flexible membrane that can be operated by means of an injection component. The present specification describes that the second channel is advantageously arranged for injecting a second medical substance for further transport to a receiving unit, e.g. a patient.

Therefore Schock concerns a completely different type of device. "Anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim." *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Company et al.*, 730 F.2d 1452, 221 USPQ 481 (Fed. Cir., 1984). A ordinarily skilled person would not look to use such a device as Schock for the injection of two medical substances since the device is intended for a totally different application. Even if a skilled person were to use the device for the injection of medical substances he/she would have to modify the device considerably in order to arrive at a device according to an embodiment of the present invention.

Claims 2-10 each depend, either directly or indirectly from independent claim 1. These dependent claims are each separately patentable, but are offered as patentable for at least the same reasons as their underlying independent base claim, whose features are incorporated by reference. Therefore, Applicant respectfully submits that the rejection has been overcome, and kindly requests favorable reconsideration and withdrawal.

Conclusion

In light of the foregoing, an early and favorable Notice of Allowability is kindly solicited.

This correspondence is being submitted electronically through the United States Patent and Trademark Office EFS Filing System on August 27, 2007

Respectfully submitted,


Max Moskowitz
Registration No.: 30,576
OSTROLENK, FABER, GERB & SOFFEN, LLP
1180 Avenue of the Americas
New York, New York 10036-8403
Telephone: (212) 382-0700